PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference PRON-028 PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/IL2004/001037	International filing date *(day/month/year)* 11 November 2004 (11.11.2004)	Priority date *(day/month/year)* 12 November 2003 (12.11.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant YEDA RESEARCH AND DEVELOPMENT CO. LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

   - ☒ Box No. I — Basis of the report
   - ☒ Box No. II — Priority
   - ☒ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV — Lack of unity of invention
   - ☒ Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI — Certain documents cited
   - ☐ Box No. VII — Certain defects in the international application
   - ☐ Box No. VIII — Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 15 May 2006 (15.05.2006)
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference see form PCT/ISA/220	Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) **FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL2004/001037	11.11.2004	12.11.2003

International Patent Classification (IPC) or both national classification and IPC
A61K39/00, A61K38/17

Applicant
YEDA RESEARCH AND DEVELOPMENT CO. LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2004/001037

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☒ contained in the international application as filed.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2004/001037

Box No. II Priority

1. ☐ The following document has not been furnished:

   ☐ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

   ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

   Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. ☒ The International Searching Authority has not been able to consider the validity of the priority claim because a copy of the earlier application whose priority has been claimed was not available to the International Searching Authority at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

4. Additional observations, if necessary:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2004/001037

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-23 (partially)

because:

☒ the said international application, or the said claims Nos. 1-15, with regard to industrial applicability, relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 1-23 (partially)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
☐ has not been furnished
☐ does not comply with the standard

the computer readable form
☐ has not been furnished
☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL2004/001037

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-23
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-23
Industrial applicability (IA)	Yes:	Claims	15-23
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Independent claims 1, 15 and 19 generally refer to neurodegenerative diseases or disorders in which there is an accumulation of misfolded and/or aggregated proteins, excluding prion-related diseases. These expressions ("neurodegenerative diseases or disorders in which ..." and "prion-related diseases") have no well-recognised meaning and leave the skilled reader in doubt as to the exact meaning of the technical features to which they refer (for instance, has the accumulation of misfolded and/or aggregated proteins to be causative, or is any degree of side accumulation of misfolded and/or aggregated proteins sufficient in order to fall within this definition), thereby rendering the definition of the subject-matter of said claims so unclear (Article 6 PCT) that a meaningful search of their subject-matter over their whole scope is not possible.
The **search**, and consequently the **examination**, of the scope of these independent claims, as well as of the claims depending on said claims, has therefore been **limited to** the diseases which are clearly disclosed in the application, i.e. **Huntington's, Alzheimer's and Parkinson's diseases** (Article 17(2)(b) PCT, Rule 70.2(d) PCT).

1.1 Moreover, the claims refer to "copolymer 1-related peptide" and to "copolymer 1-related polypeptide". These expressions have no well-recognised meaning and leave the skilled reader in doubt as to the exact meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claims unclear (Article 6 PCT).
The definition provided in the description with regard to the meaning of said expressions (pages 15-22) is also extremely vague and broad, so that a meaningful search, and examination, over the whole scope of the claims is not possible.
The **search**, and consequently the **examination**, of the scope of the claim has therefore been **limited to Copolymer 1** (Article 17(2)(b) PCT, Rule 70.2(d) PCT).

2. Claims 1-14 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with

respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. For the assessment of the present claims 1-14 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

2. Document **D1** (Program No. 440.1. 2003 Abstract Viewer/Itinerary Planner. Washington, DC: Society for Neuroscience, 2003. Online) discloses that administering Copolymer-1 protects in an experimental model of Parkinson's disease. Documents **D2** (WO-A-01/97785; e.g. page 11, lines 19-22) and **D3** (Drug Development Research, 2002, **56**:143-149; e.g. page 147, left-hand column, 1st paragraph - right-hand column) disclose that administering Copolymer-1 is expected to be effective to treat Alzheimer's disease.
Document **D4** (WO-A-01/93893; e.g. claim 5) discloses that administering Copolymer-1 is expected to be effective to treat Alzheimer's, Huntington's and Parkinson's diseases. Document **D5** (WO-A-01/52878; e.g. pages 11 and 33) also discloses that administering Copolymer-1 is expected to be effective to treat Alzheimer's, Huntington's and Parkinson's diseases. D5 moreover teaches that Copolymer 1 protects against glutamate toxicity.

Documents **D6** (Trends in Molecular Medicine, 2002, **8**(7):319-323; e.g. paragraph bridging pages 321 and 322) and **D7** (Cellular and Molecular Neurobiology, 2001, **21**(6):617-627; e.g. abstract) also refer to the use of Copolymer 1 to treat Alzheimer's disease.
Documents D1-D7 hence disclose the subject-matter of independent claim 1 and of dependent claims 2-5, which is hence not novel. Claims 1-5 do hence not meet the requirements of Article 33(2) PCT.

2.1 The subject-matter of independent claims 6-14 does not differ from that of independent claim 1.
The subject-matter of independent claims 6-14, and of dependent claim 14, does hence not meet the requirements of Article 33(2) PCT.

2.2 With the exception of a **first** medical use, the intended use of a product is not a technical feature of the product *per se*. In other words, a claim defining a "product for a particular use" actually defines said product as being "suitable for" said particular use (see the Guidelines 5.23 *and seq.*).
The products of claims 15-18, 22 and 23 are therefore identical to those defined for medical uses in D1-D7, hence lacking novelty.
The subject-matter of claims 15-18, 22 and 23 does thus not meet the requirements of Article 33(2) PCT.

2.3 In addition, the arguments presented herein-above also apply for the "second medical uses" defined in claims 19-21.
Claims 19-21 do hence not meet the requirements of Article 33(2) PCT with regard to novelty.

Additional Comments

3. Although claims 1 and 6-13 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought

and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.